WHAT IS CLAIMED IS:

1. A viable and stable probiotic formulation for intestinal targeting, comprising:

a plurality of probiotic microspheres each comprising:

-a core comprising one or more probiotic bacteria, a cellulosic excipient, a disintegrant and one or more additives; and

-an enteric coating capable of being resistant to gastric fluids,

having a residual moisture level of less than 5% and a water activity (a_w) between 0.1 and 0.5.

2. The probiotic formulation according to claim 1, wherein said residual moisture level is less than 2 %.

3. The probiotic formulation according to claim 1, wherein said water activity (a_w) is between 0.15 and 0.35.

4. The probiotic formulation according to claim 1, having no reduction in viable bacteria after 1 hour exposure to simulated gastric fluids.

5. The probiotic formulation according to claim 4, comprising:

a moisture protective and controlled disintegration non-enteric coating as an undercoat to the enteric coating.

6. The probiotic formulation according to claim 5, wherein said non-enteric coating comprises:

-one or more non-enteric agents selected from the group consisting of polyvinyl alcohol (PVA), hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), sodium carboxymethyl cellulose (Na-CMC), ethylcellulose (EC), waxes, fatty acids, fatty alcohols, fatty esters; and

- a plasticizing agent selected from the group consisting of diethyl phthalate, dibutyl sebacate, triethyl citrate, acetyltriethyl citrate, tributyl citrate and polyethylene glycol.

7. The probiotic formulation according to claim 6, wherein said plasticizing agent is selected from the group consisting of triethyl citrate and diethyl phthalate.

8. The probiotic formulation according to claim 6, wherein the cellulosic excipient is a microcrystalline cellulose (MCC).

9. The probiotic formulation according to claim 8, wherein said MCC has a degree of polymerization (DP) from 165 to 365 and a mean diameter from 45 to 180 μm.

10. The probiotic formulation according to claim 9, wherein said DP is from 220 to 230 and said mean diameter is from 45 to 55 μm.

11. The probiotic formulation according to claim 1, wherein said enteric coating comprises:

- an agent selected from the group consisting of polymers or copolymers of acrylic acid and/or methacrylic acid and/or their esters, cellulose acetate phthalate, polyvinyl acetate phthalate and shellac; and

-a plasticizing agent being selected from the group consisting of diethyl phthalate, dibutyl sebacate, triethyl citrate, acetyltriethyl citrate and tributyl citrate.

12. The probiotic formulation according to claim 11, wherein the enteric coating agent is selected from the group of methacrylic acid-ethyl acrylate copolymer and cellulose acetate phthalate.

13. The probiotic formulation according to claim 11, wherein said plasticizing agent is selected from the group consisting of triethyl citrate and diethyl phthalate.

14. The probiotic formulation according to claim 8, wherein said additives comprise one or more stabilizer.

15. The probiotic formulation according to claim 14, wherein the core comprises in weight percentage of the total dry weight of the core:

-from 1 to 10% of said probiotic bacteria;

-50 to 90% of said MCC;

-from 0.1% to 30% of said stabilizer; and

-from 0.1% to 5% of said disintegrant.

16. The probiotic formulation according to claim 15, wherein it comprises in weight percentage of the total dry weight of each microsphere:

from 5 to 30% of said non-enteric coating; and

from 5 to 30% of said enteric coating.

17. The probiotic formulation according to claim 16, wherein the non-enteric coating is present at a concentration from 10 to 20%.

18. The probiotic formulation according to claim 16, wherein the enteric coating is present at a concentration from 10 to 20%.

19. The probiotic formulation according to claim 1, wherein said core of the microspheres has a diameter ranging from 150 to 3000 µm.

20. The probiotic formulation according to claim 19, wherein said core has a diameter ranging from 425 to 2000 µm.

21. The probiotic formulation according to claim 1, wherein the probiotic bacteria are selected from the group consisting of Lactobacillus, Bifidobacterium, Enterococcus, Propionibacterium, Bacillus and Streptococcus.

22. The probiotic formulation according to claim 21, wherein the probiotic bacteria are selected from the group consisting of Lactobacillus and Bifidobacterium.

23. The probiotic formulation according to claim 15, wherein said stabilizer is selected from the group consisting of glycerol, non-fat skim milk powder, ascorbic acid, anthocyanidins, flavanols, betaine, nicotinin acid, peptone, tryptone, cysteine, sodium chloride, trehalose, sucrose, short-chain fructo-oligosaccharides (scFOS), oligofructose, whey protein isolate, adonitol, meat extract and yeast extract.

24. The probiotic formulation according to claim 23, wherein the stabilizer is selected from the group consisting of peptone, tryptone and scFOS.

25. The probiotic formulation according to claim 15, wherein the disintegrant is selected from the group consisting of croscarmelose sodium, crospovidone, sodium starch glycolate, alginic acid and starch.

26. The probiotic formulation according to claim 25, wherein said disintegrant is croscarmelose sodium.

27. A process for preparing a probiotic formulation as defined in claim 1, said process comprising the steps:

-dry blending a microcrystalline cellulose (MCC) with a disintegrant;

-granulating said mixture of MCC and disintegrant with an aqueous dispersion comprising a lyophilized probiotic powder, stabilizers and purified water in order to form an extrudable paste;

-extruding said extrudable paste in the form of segments;

-spheronizing segments to form cores as defined in claim 1;

-drying the cores to a residual moisture level of less than 5 % and a water activity (a_w) between 0.1 and 0.5; and

-coating said cores to obtain the microspheres;

said process giving less than 1.5 loss of log colony-forming units (cfu) per gram on a dry basis at the end of the coating steps.

28. The process according to claim 27, wherein said residual moisture level is less than 2 %.

29. The process according to claim 27, wherein said water activity (a_w) is between 0.15 and 0.35.

30. The process according to claim 27, wherein said MCC has a degree of polymerization (DP) from 165 to 365 and a mean diameter from 45 to 180 µm.

31. The process according to claim 30, wherein said MCC has a degree of polymerization (DP) from 220 to 230 and a mean diameter from 45 to 55 µm.

32. The process according to claim 27, wherein said disintegrant is selected from the group consisting of croscarmelose sodium, crospovidone, sodium starch glycolate, alginic acid and starch.

33. The process according to claim 27, wherein said probiotic powder is selected from the group consisting of Lactobacillus, Bifidobacterium, Enterococcus, Propionibacterium, Bacillus and Streptococcus.

34. The process according to claim 33, wherein said probiotic bacteria are selected from the group consisting of Lactobacillus and Bifidobacterium.

35. The process according to claim 27, wherein the cores obtained in the spheronizing step have a diameter ranging from 150 to 3000 µm.

36. The process according to claim 35, wherein said diameter of the cores ranges from 425 to 2000 µm.

37. The process according to claim 27, wherein the step of coating comprises the steps of:

- covering said cores with a moisture protection and controlled disintegration non-enteric coating; and
- covering said non-enteric coating with an enteric coating capable of being resistant to gastric fluids.

38. The process according to claim 37, wherein said non-enteric coating comprises:

-one or more non-enteric agents selected from the group consisting of polyvinyl alcohol (PVA), hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), sodium carboxymethyl cellulose (Na-CMC), ethylcellulose (EC), waxes, fatty acids, fatty alcohols, fatty esters; and

- a plasticizing agent selected from the group consisting of diethyl phthalate, dibutyl sebacate, triethyl citrate, acetyltriethyl citrate, tributyl citrate and polyethylene glycol.

39. The process according to claim 37, wherein said enteric coating comprises:

- an agent selected from the group consisting of polymers or copolymers of acrylic acid and/or methacrylic acid and/or their esters, cellulose acetate phthalate, polyvinyl acetate phthalate and shellac; and

-a plasticizing agent being selected from the group consisting of diethyl phthalate, dibutyl sebacate, triethyl citrate, acetyltriethyl citrate and tributyl citrate.